(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 27 February 2003 (27.02.2003)

PCT

(10) International Publication Number WO 03/016175 A1

(51) International Patent Classification⁷: 75/30, G02C 7/04, A45C 11/00

B65D 85/38,

(21) International Application Number: PCT/AU02/01105

(22) International Filing Date: 17 August 2002 (17.08.2002)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

PR 7086

17 August 2001 (17.08.2001) A

(71) Applicant (for all designated States except US): CLEAR-LAB PTE LTD [SG/SG]; #06-02, 139 Joo Seng Road, Singapore 368362 (SG).

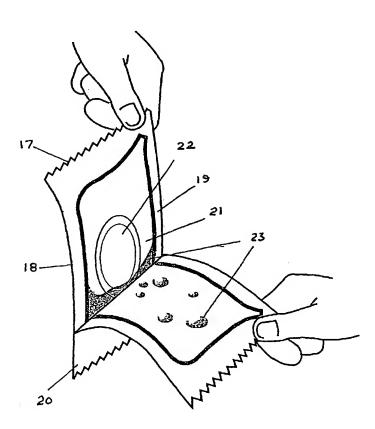
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): NEWMAN, Stephen,

Donald [AU/AU]; #27-05 Pearl Tower, 62 Bayshore Road, Bayshore Park (SG).

- (74) Agent: WALSH, John, Richard; C/- Walsh & Associates, Patent and Trade Mark Attorneys, P.O. Box 4306, Penrith Plaza, New South Wales 2750 (AU).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

[Continued on next page]

(54) Title: PACKAGING FOR DISPOSABLE SOFT CONTACT LENSES



(57) Abstract: A single use package capable of holding a contact lens (22) therein, the packaging comprising at least one barrier layer (16,17) of flexible/pliable package material forming at least first (16) and second (17) opposing surfaces which define an internal package space (21) in which the contact lens (22) is retained, a medium (23) in the space for maintaining lens hydration, and means for enabling release of said contact lens from said package, wherein said at least one barrier layer of material is capable of assuming a generally coplanar configuration and is/are not preformed.

WO 03/016175 A1

ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

with international search report

PACKAGING FOR DISPOSABLE SOFT CONTACT LENSES.

BACKGROUND

5

10

15

20

25

The present invention relates to contact lens packaging and more particularly relates to an improved economic form of package for a contact lens which satisfies lens packaging criteria including sterility and environmentally sensitive disposability.

PRIOR ART

Soft disposable contact lenses are commonly contained in disposable packages. As packaging adds to the overall cost of the lens it should be made as economically as possible but without compromise to the requisite packaging criteria. The traditional packaging for disposable lenses (both two weekly and daily) consists of a polypropylene "boat" or receptacle for the lens, topped by a multi-layer film of polyethylene, Aluminium, bonding agent and Polypropylene. The boat is filled with a suitable storage solution preferably saline and receives the lens in situ. The "boat" or blister pack is then autoclaved using steam and pressure to terminal sterility. These blister packs are presented to the patient in boxes of individual or as multiple blister strips. The marketing objective is to be able to present the contact lens to a patient in an aesthetically pleasing package that both satisfies the statutory requirements for sterility and stability and allows the patient to remove the lens safely and easily. The packaging is used only once and is discarded after the lens is removed. This impacts on the costs of lens/package combination. In order to reduce the overall price of the lens to the patient, the cost of the packaging should

be kept to an absolute minimum. Disposability of lens packages places an onus on conformity to the required ecological requirements. The packages should present the least problematic ecological threat as is possible. The above packages are known generically as blister packs and generally hold a single contact lens. The packs typically consist of two pieces the first being the moulded or preformed blister pack

5

10

15

20

(sometimes referred to as a boat) and a cover. The boat is usually an injection moulded plastics which has high stiffness but is capable of limited elastic deflection and includes a preformed recess in which the contact lens is placed. The cover is typically a laminated material comprising mostly Aluminum and polypropylene. The package must be well sealed and should minimize gas transmission through the "boat" and laminated layer to maximize the shelf life and prevent drying out of the lens contained in the package. The lens must be kept hydrated whilst in the package. In use, the user removes the laminated material from a flange formed on the "boat" by peeling back to expose the lens immersed in a hydrating solution. A variety of contact lens packages and particularly disposable contact lens packages including preformed blister packs are taught in the prior art.

One example of a known contact lens packaging is disclosed in United States patent 5,704,468. That patent teaches a packaging arrangement for the containment in a blister pack of a hydrophilic contact lens in a sterile aqueous solution. The packaging includes a form of stiffening groove or wall elements in flanges of base members of the blister packages housing to facilitate an improved attachment

between the base members of the blister package housing the lens and a flexible cover sheet utilized for sealing engagement with the base members while incorporating additional strength to the blister package structures.

United States patent 4,392,569 discloses an asepticizing case for the storage and transport of soft contact lenses wherein each lens is confined on a curved surface in a fluid environment without the direct application of force thereto. The case includes a flexible skirt of having a smaller radius of curvature than that of the lens receiving surface is affixed to the cap to insure the positioning of each lens.

5

10

15

20

Another packaging arrangement for a hydrophilic contact lens is disclosed in United States patent 5,620,088. The packaging arrangement disclosed houses a contact lens in a sterile aqueous solution. More specifically the arrangement discloses a plurality of disposable hydrophilic contact lenses in a specific number of individual packaging arrangements collectively housed in a box like container so as to provide a specified or essentially measured supply of contact lenses for use by a consumer over a predetermined period of time.

A further packaging for holding a contact lens is disclosed in United States patent 4,691,820 which describes a moulded blister package for storing and dispensing a hydrophilic contact lens. The package comprises a base portion which includes a cavity surrounded by an outstanding flange and a cover sheet sealed to the flange to enclose the cavity. A portion of the side wall of the cavity is inclined to form a ramp to the flange. The cover sheet may be stripped from the flange to expose the cavity and inclined side wall whereupon the lens is readily removed by sliding up and out of the cavity along the inclined surface.

Another packaging arrangement is disclosed in United States patent 5,823,327 which describes a base member for a blister package for the containment of a contact lens and which includes a planar flange extending outwardly about a cavity for housing the contact lens. A proximate peripheral edge of the flange includes a continuous groove into which there is pressed the material of a flexible cover sheet of the blister package so as to clampingly engage the base member.

5

10

15

20

Flexible retort packages are also known, but not in use with contact lenses. One such package is disclosed in United States patent 4,769,261. That patent teaches a seal layer for use in large institutional sized retort pouches comprising an ABA film structure wherein the A layers are each composed of a blend of a minor amount of an elastomer and a major amount of a polyolefin and the B layer is composed of a blend of a major amount of an elastomer and a minor amount of polyolefin. Retort pouches made with the ABA film structure as the seal layer exhibit improved impact strength. Conventional wisdom in the contact lens industry has been to provide preformed stiff packaging which protects the lens from external impact damage from applied loads.

United States Patent 5853085 discloses a disposable holding and cleaning apparatus for a contact lens and which includes an open end for holding one or more contact lenses. The envelope is divided by a horizontal seam and vertical seam in order to form a pair of lens storage compartments and fluid storage compartments. Several ports are includes in the package to facilitate

communication between the fluid and the lens storage compartments. When manual pressure is exerted on the balloon the balloon bursts and disperses lens cleaning solution onto the lens storage compartments through the ports for cleaning the lenses. This arrangement enables holding of contact lenses and lens care solution in air tight condition and prevents accidental loss of the contact lens. The packaging arrangements for holding contact lenses disclosed in that patent is intended as a cleaning method for contact lenses rather than a flexible mass produced economic package for holding and transporting lenses. A disadvantage of this lens package in United States Patent 5853085 is that it is expensive to manufacture and is complex in construction.

5

10

15

20

Other examples of contact lens packages are disclosed in European Patents EP 1 092 645 A1 to Johnson and Johnson and EP 0 129 388 to Ruxley Holdings Limited. EP 1 092 645 discloses a disposable package for a contact lens which employs an injection moulded blister pack sealed by a laminated layer of plastics and aluminum foil. That patent discloses an example of the well known blister packages which includes a magnifying lens to enable a user to read lens indicia. The package disclosed is potentially resealable and there is no teaching in this patent of a retort style package for a contact lens.

EP 0 129 388 also discloses a package specifically for measurement of one or more optical parameters of a contact lens wherein the lens is housed on an "optically acceptable" plastics film containing and aqueous fluid and a contact lens.

The known contact lens packages have a number of disadvantages which include the following:

The packages are relatively expensive for daily disposable packages as they use
two types of material one of which is preformed increasing manufacturing costs.
Consumers resist packages which contribute to increased cost of a lens. This will
become even more of a problem as the daily disposable market grows and becomes

5

15

20

more competitive.

- 2. Prior art packages are traditionally manufactured from two distinctly different materials which are used to make up a blister which houses the lens. This can lead to sealing problems with an attendant risk of compromised sterility. Over time, a poor sealing blister pack can allow its contents to evaporate and render the pack useless. This could cause stock defects and consequent financial losses to the manufacturer. Correction of the defects would be potentially expensive.
 - 3. Should the patient receive a non sterile lens due to poor or incomplete package sealing, there could be the possibility of that patient being subjected to an eye infection with the risk of ocular compromise and resultant litigation.
 - 4. The size of the packaging is a disadvantage to the disposable lens concept as the receptacle is many times larger than the lens itself. As a result of the polypropylene blister component the individual component is somewhat deeper than the lens from a sagittal perspective and as such does not lend itself to a disposable look nor convenient stacking due to its bulk. If the consumer travels, the lenses can prove to be quite a bulky item.

5 The traditional approach to lens packaging has been to ensure that the original shape of the lens is maintained in the package. This philosophical approach places limitations on package configurations.

There is a long felt want in the disposable contact lens industry to provide an economic, space efficient and convenient disposable contact lens package without compromise to durability, sterility and utility of the lens.

SUMMARY OF THE INVENTION

5

10

15

20

The present invention seeks to ameliorate the problems of the prior art packages by providing an alternative and more economic package but without compromise to the statutory and medical requirements of contact lens packages.

Conventional wisdom requires a disposable contact lens package to be stiff and preformed with a profiled recess to house the lens therein. The preformed recess in the known packages is intended to ensure that the lens shape is maintained and is not deformed by the package. Retort style packaging on the other hand is contrary to conventional wisdom as it is flexible and not preformed and can contribute to adjustments to the shape of the lens in the package. The present invention challenges the long held view that disposable lens packages must be stiff and for the most part rigid and capable of elastic deflection under load. Stiffness of the package was previously thought essential to protect the lens. If wall stiffness is abandoned as an essential packaging criteria this opens alternative storage possibilities for contact lens packages with significant space economy.

The present invention according to one embodiment, offers an alternative solution for packaging of disposable contact lenses by employing a packaging material

which provides the requisite maintenance of hydration and protection for a lens therein and which may be stacked flat for optimum space economy. According to one embodiment, the lens package is manufactured from one piece of the package material. The package preferably consists of identical but flexible materials approved by the various contact lens regulatory authorities around the world whilst remaining simple in construction.

In its broadest form the present invention comprises:

5

20

a single use contact lens package made from one piece and from one pliable material.

In another broad form the present invention comprises:

a disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made in one piece and of one pliable material. According to a preferred embodiment the lens is contained in a retort package.

According to another embodiment the retort package is capable of conforming partially or wholly with the contact lens.

In another broad form the present invention comprises:

a disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made in one piece and of one material wherein the package is a pliable and flexible retort package.

In another broad form the present invention comprises:

a single use disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made from one or

two pieces of the same material wherein the package is a pliable and flexible retort package; wherein said material can be folded back on itself to form said package.

According to one embodiment, access to a lens in said package is via at least one sealed edge of said package.

In another broad form according to a method aspect, the present invention comprises:

a method of producing a disposable contact lens package comprising the steps of:

a) taking a single sheet of pliable material;

5

15

- 1b) folding said material back on itself to define an envelope to receive a at least one contact lens;
 - c) sealing said envelope so that said contact lens is held in a sterile aqueous solution;
 - d) allowing access to said package by splitting or dividing said package along at least one edge.

According to one embodiment the edges of said package are heat sealed.

According to a preferred embodiment the lens resides in said solution inside said package.

In another broad form the present invention comprises;

a single use package capable of holding a contact lens therein, the packaging comprising:

at least one barrier layer of flexible/pliable package material forming at least first and second opposing surfaces which define an internal package space in which the contact lens is retained;

a medium in the space for maintaining lens hydration; and

5

10

15

20

means for enabling release of said contact lens from said package; wherein the at least one barrier layer of material is capable of assuming a generally planar configuration and is not preformed.

Preferably each said at least first and second opposing surfaces oppose an anterior and /or posterior surface of said contact lens. The means for releasing the contact lens from the package comprises peeling away one of said barrier layers from the other layer.

The barrier layers are capable of mutual deformation responsive to a load applied to the package. Preferably the barrier layers are formed from two pieces which provide the two opposing inner surfaces which define said space in which said lens is held. Opposing edges of the barrier layers are preferably heat sealed. The hydration maintenance medium also provides a buffer to dissipate energy generated by external loads applied to the package at or near the location of the lens. The lens hydration maintenance medium is a suitable storage solution which may be, but not limited to, a saline based solution. Each barrier wall of the package may be laminated and include a metallic layer such as but not limited to aluminium. Each barrier layer further comprises an outer layer of protective material and an inner layer of polypropolyene which engages an outer surface of

the metallicised layer. The polypropylene layer engages an inner surface of the metallicised layer.

According to another embodiment at least one package is detachably connected to other like packages such that a set of at least two like packages are formed wherein each package is connected to an adjacent package via a frangible connection.

An additional package may be connected to a contact lens package and includes therein a source of lens hydration maintenance medium.

The barrier layers of the package may be formed from the same or different materials.

- In another broad form of a method aspect, the present invention comprises;

 a method of producing a disposable contact lens package comprising the steps of:
 - a) taking a single sheet of pliable material;

- b) placing a lens on a surface of the sheet;
- c) dosing the surface of the material with a predetermined hydration medium;
- d) folding said material back on itself to define a space in which the contact lens is held:
 - e) sealing said envelope so that said contact lens is held in a sealed environment;
 - f) allowing access to said lens by splitting or dividing said package along at least one edge.
- According to a preferred embodiment the method comprises the further step following sealing the lens package, of sterilizing the package by autoclaving.

 In another broad form the present invention comprises; a single use package for retaining a contact lens: the package comprising at least one barrier material

defining an internal space fore holding a contact lens in a medium for maintaining lens hydration in a sealed environment; means to enable release of the lens from said space; wherein the at least one barrier layer is formed from a homogenous, pliable material.

The barrier material is pliable allowing the package to be deformed, flattened, twisted, bent folded or rolled in unison with the lens and without compromise to the integrity of the lens therein.

In another broad form, the present invention comprises;

5

10

15

a set of single use retort packages for holding contact lenses therein; the packages each comprising at least one barrier layer of flexible/pliable package material forming at least first and second opposing surfaces which define an internal package space in which the contact lens is retained;

a medium in the space for maintaining lens hydration; and

means for enabling release of said contact lens from said package; wherein the at least one barrier layer of material is capable of assuming a generally planar configuration and is not preformed; wherein the set is formed by joining at least two said packages end to end so that a single package may be torn away from an adjacent package via a frangible connection between the packages.

In its broadest form the present invention comprises;

a single use generally planar pliable retort package for holding a contact lens.

In another form the present invention comprises; a strip of joined single use retort packages for holding a contact lens; wherein each single use package is connected to an adjacent package via a frangible connection.

In another broad form the present invention comprises;

a kit of joined single use pliable retort packages for each holding a contact lens; wherein each single use package is connected to at least one adjacent package.

In another broad form the present invention comprises;

a single use package capable of holding a contact lens therein, the packaging comprising:

at least one barrier layer of flexible/pliable package material forming at least first and second opposing surfaces which define an internal package space in which the contact lens is retained;

a medium in the space for maintaining lens hydration; and
means for enabling release of said contact lens from said package; wherein said at
least one barrier layer of material is capable of assuming a generally co planar
configuration and is/are not preformed.

15

DETAILED DESCRIPTION

The present invention will now be described according to a preferred, but non limiting embodiment and with reference to the accompanying illustrations: wherein;

Figure 1 shows a plan view of a typical prior art disposable blister contact lens package.

Figure 2 shows a side elevation of the package of figure 1 with lid peeled away to release the contact lens therein.

Figure 3 shows a perspective view of the package of figure 2.

Figure 4 shows a stacking arrangement for two identical prior art contact lens packages according to one embodiment.

- Figure 5 shows a plurality of blister packs stacked as in figure 4 and contained in a carton.
- Figure 6 shows a perspective view of a retort package according to a preferred embodiment of the invention.
 - Figure 7 shows the retort package of figure 6 with the contact lens exposed by peeling a layer.
 - Figure 8 shows a strip of retort packages.

15

- Figure 9 shows the strip of retort packages of figure 8 including a hydrating solution pack.
 - Figure 10 shows a carton containing a large number of envelopes holding retort package strips according to a preferred embodiment.
 - Throughout the specification the term homogenous should be taken to be a reference to a package wall formed from a single layer (i.e., non laminated layer) of the same material. The package described may also be made from a multi layer laminated material which may be formed from a combination of suitable plastics or a combination of suitable plastics and a metallic layer as described herein.
 - Referring to figure 1 there is shown a plan view of a typical prior art disposable blister contact lens package 1 which is formed in two parts. Figure 2 shows a side elevation of the package 1 of figure 1. Package 1 comprises a blister pack 2 which is sealed by a membrane 3 forming a lid on pack 1 and which may be peeled away to release contact lens 4 therein. Figure 3 shows a perspective view of the

package of figure 2 with membrane 2 peeled away to expose contact lens 4. Typically member 2 will be a preformed blister pack and includes a profiled recess 5 which in whole or in part either conforms to the shape of a lens or provides a recess in which a lens may be placed. The injection moulded pre formation makes this is an expensive package to manufacture with the result that the lens will inevitably be more expensive for the consumer. Member 2 is typically injection moulded and the package is completed with sealing membrane 3 which mates with flange 6 to effect a sterile seal. Lens 4 is immersed in a solution 7 which maintains lens hydration keeps the lens hydrated until it is removed from the pack.

5

1.0

15

20

Figure 4 shows a stacking arrangement according to one embodiment for two identical prior art contact lens packages 10 and 11. It can be seen from figure 4 that although two packs conveniently interfit they take up a thickness greater than the thickness (or depth) of two packs. Ideally a lens package should take up as little space as possible considering the relatively small size of a contact lens. Economy of storage space is a critical issue where lenses are mass produced. The existing blister packs take up a disproportionate amount of space relative to the size of the lens leading to increased handling and storage costs. Figure 5 shows a plurality of like blister packs 12 stacked as in figure 4 and retained in a carton 13. This space taking, inconvenient and materials intensive form of lens packaging exists as a result of the conventional wisdom suggesting that lenses cannot be stacked other than in rigid containers which isolate the lens from external load.

5

10

15

20

Referring to figure 6 there is shown a perspective view of a retort package 14 according to one embodiment of the invention. Package 14 comprises a layered flexible envelope for holding a lens and which may be formed from one piece or two pieces of like or different flexible material. According to one embodiment package 14 is manufactured from a single piece of a flexible laminated material which is strong enough to protect a lens held in a space formed in the package but flexible enough to withstand a variety of applied loads such as but not limited to, bending, folding, twisting, rolling or crushing. The wall of the package which is preferably a homogenous material does not necessarily conform to the shape of a lens but rather the lens "floats" in the package. The package may be formed by folding a homogenous material back on itself and sealing the edges to form a sterile envelope. Alternatively, the package may be formed from a homogenous material from two opposing pieces heat sealed along their edges in opposing relationship. Access to the lens is gained by dividing the package along one or more predetermined heat sealed edges. Referring to figure 6, package 14 comprises first and second barrier layers 15 and 16 which may be formed by folding one layer or by joining two separate barrier layers. Barrier layers 15 and 16 are heat sealed around edges 17, 18, 19 and 20. The heat sealing of edges 17 - 20 provide a boundary defining an internal space 21 in which a lens 22 is housed. Lens 22 is immersed in a predetermined minimum amount of solution 23 which keeps the lens hydrated (see figure 7). To release and expose the lens, layer 16 is peeled away from layer 17. Alternatively, layer 17 may be peeled away from layer 16. To facilitate initial release of layers, a portion of the mating engagement

between layers is lightly sealed preferably at a corner to enable separation of the barrier layers. Figure 7 shows the package of figure 6 torn open to release lens 22. According to one embodiment, the barrier layers 16 and 17 are multi layer laminates comprising materials which enable compliance with statutory requirements for lens packages. For example, a typical lens package material may comprise a PET (polyethylene tarepthelate) layer, an aluminium layer and a polyolefin layer such as polypropylene. A packet of a predetermined size may be formed from barrier layers of the same or different materials. According to one embodiment the package may be formed by folding a single strip of material back on itself to form the space therein for holding the lens. In another embodiment two separate strips of the same or different material in opposing engagement are heat sealed at their edges. A thin layer of Aluminium has properties such as inherent pliability and inhibition of oxygen transmission which make it a good material as part of the barrier wall composites. According to one embodiment, a lamination profile of a barrier material may comprise an outer layer of PET of 10 µ, an aluminium layer of 50 μ a polypropylene layer of 50 μ .

5

10

15

20

Figure 8 shows a strip of retort packages 30, 31 and 32 held together by frangible joins 33 and 34. The lens packages may be separated one at a time by tearing off at joins 33 and 34. Also, the strips may be folded about joins 33 and 34 which contributes to efficient storage and packaging. Thus 6 -8 and possibly more lenses could potentially be stored in the same space as two lenses using prior art blister packs.

Figure 9 shows the strip of retort packages 30 - 32 of figure 8 including a hydrating solution pack 35 attached to package 30 via a frangible join 36. Pack 35 may be used by the consumer to hydrate the lens should supplementary lens hydration be required.

Figure 10 shows an exploded view of a carton 40 containing a large number of like envelopes 41 holding retort package strips 42 according to a preferred embodiment. It can be seen from this arrangement that a larger number of lenses may be stored per unit space compared to prior art packaging. Up to and depending upon the tightness of the packaging more than 10 lenses may be stored in a space which would previously have been taken by two lens packages.

5

10

15

20

The manufacturing of disposable lenses becomes more cost effective as the cost of packaging the lens is reduced and the efficiency of sealing and subsequent sterilising is improved. From the patient's perspective the lens can appeal more as a disposable item, takes up far less space and can be packaged in a more appealing fashion. This type of packaging especially suits daily disposable lenses as the cost component of this type of packaging is attractive to a consumer and manufacturer. The form of retort packaging described would preferably contain one soft contact lens each. The appropriate art work and statutory information may be printed on the external surfaces in a similar fashion to the current packaging.

The integrity of the lens in this "flat" style packaging is preserved by a surrounding buffer of storage medium in the packet. The storage medium may also act as a safety buffer if the lens packet is subjected to rough or potentially damaging treatment. The current blister pack offers lens barrier protection through use of the

injection moulded and pre formed rigid blister component. However, as the conventional blister package includes an aluminium foil bridging an opening to the blister pack, the unsupported foil offers no more protection and on the foil side potentially less protection than a retort package with two flexible barrier layers which respond more favorably to applied loads. In fact, the aluminium surface of the blister packs can be more easily punctured due to it's tightness over the polypropylene "boat". The retort style packaging is inherently soft and can deflect potential punctures by moving with the puncturing object.

5

10

15

20

According to one embodiment the solution employed for maintenance of hydration of the lens is a saline solution. The package allows for a sufficient minimum of solution for maintenance of hydration and does not require that the lens swim in hydrating solution as in the prior art packages. In the prior art blister packs, the lens 'swims' in a bath of hydration maintenance solution disposed in preformed recess.

In the package according to the invention, excess hydration maintenance fluid may be forced out during the manufacturing process leaving a predetermined minimum of solution or gel to keep the lens hydrated. Due to the optimal sealing qualities of the retort package no vapour will escape from the internal space. The flatness of the package barrier layers will facilitate sticking of the lens to one or other of the internal surfaces providing the advantage that when a layer is peeled back to expose the lens inside the lens will be stuck to an inner surface which ensures that the lens will not drop out during opening.

Advantages of the retort style packaging include the following;

1 More homogenous packaging than the known packages with the attendant improvements in sealing and subsequent sterilising

- 2 Smaller and slimmer (flatter) packaging lends itself to disposability which makes it ideal for traveling.
- 5 3 The flatter pack saves weight and space due to flat storage.
 - 4 Less packaging material per lens compared to the prior art packages.
 - 5 More cost effective than current types of packaging thus allowing for a reduction in cost of lenses to consumers.
 - 6 The use of a metallic foil (such as but not limited to Aluminium) foil stabilizes light and prevents unwanted O₂ transmission.
 - 7 The package is not re useable or resealable.

10

- 8 As air is not used in the package non ballasted autoclaving is not required.
- 9 Absence of air in the package may contribute lens stability within the package.
- 10 As the package is significantly smaller and slimmer than the prior art packages batch sizes may be increased yet storage space in an end users package may be reduced.
 - 11 Secondary packaging can be more compact and package walls/barrier layers of the package are flexible /pliable which enables the whole package to be deformed or worked by bending, twisted, folded or rolled. Thus the package could be stored rolled in a tube for instance.
 - 12 Contact lenses may now be packaged without the previous package design constraint that the basic lens shape be retained.

It will be recognized by persons skilled in the art that numerous variations and modification may be made to the invention as broadly described herein without departing from the overall spirit and scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

5

10

15

1 A single use package capable of holding a contact lens therein, the packaging comprising:

at least one barrier layer of flexible/pliable package material forming at least first and second opposing surfaces which define an internal package space in which the contact lens is retained;

a medium in the space for maintaining lens hydration; and means for enabling release of said contact lens from said package; wherein said at least one barrier layer of material is capable of assuming a generally co planar configuration and is/are not preformed.

- 3 A package according to claim 2 wherein the package material/s is/are capable of mutual deformation responsive to a load applied to the package.
- 4 A package according to claim 3 wherein the hydration maintenance medium provides a buffer to dissipate energy generated by external loads applied to the package.
- 5 A package according to claim 4 wherein the package material comprises a single layer of the same material.
- 6 A package according to claim 4 wherein the package material comprises two single layers sheets of different materials
- 7 A package according to claim 4 wherein the package material comprises two single layer sheets of the same material.
 - 8 A package according to claim 4 wherein the package comprises a single sheet of multi layer material.

9 A package material according to claim 4 wherein the package comprises two sheets of like multi layer material.

- 10 A package according to claim 4 wherein the package comprises two sheets of different multi layer material.
- 11 A package according to any of the foregoing claims wherein, the means for releasing the contact lens from the package comprises separating the opposing surfaces by peeling or tearing the package.
 - 12 A package according to claim 11 wherein opposing edges of the opposing surfaces are heat sealed.
- 13 A package according to claim 12 wherein the medium is saline based.

- 14 A package according to claim 13 wherein, the lens hydration maintenance medium is saline solution.
- 15 A package according to claim 14 wherein, the lens in said space is free to move inside the space defined by the opposing inner surfaces and edges of the space.
- 16 A package according to claim 15 wherein, each said at least first and second opposing surfaces oppose an anterior and /or posterior surface of said contact lens;
- 17 A package according to claims 8 or 9 wherein, the multi layer material includes a metallic layer.
- 20 18 A package according to claim 17 wherein the multi-layer material further comprises an outer layer capable of displaying product indicia and sealing any inner layers from an external environment.

19 A package according to claim 18 further comprising an appropriate polyolefin layer.

- 20 A package according to claim 19 wherein the outer layer engages an outer surface of a layer of aluminium.
- 5 21 A package according to claim 20 wherein the polyolefin layer comprises a polypropylene layer which engages an inner surface of the aluminium layer.
 - 22 A package according to claim 1 or 21 having connected thereto at least one other like package such that a set of at least two like packages are formed.
 - 23 A package according to claim 22 wherein each package is connected to an adjacent package via a frangible connection.
 - 24 A package according to any of the foregoing claims further comprising an additional package connected to said contact lens package and having therein a source of lens hydration maintenance medium.
 - 25 A package according to claim 24 wherein the package material is pliable allowing the package to be deformed, flattened, twisted, bent, folded crushed or rolled in unison with the lens and without compromise to the integrity of the lens therein.
 - 26 A package according to claim 5 wherein the space is formed by folding a single sheet of said flexible material back on itself and heat sealing opposing edges of the sheet.
 - 27 A method of producing a disposable contact lens package comprising the steps of:
 - a) taking a single sheet of pliable material;

10

15

- b) placing a lens on a surface of the sheet;
- c) dosing the surface of the material with a predetermined hydration maintenance medium;
- d) folding said material back on itself to define a space in which the contact lens is held;
 - e) sealing said envelope so that said contact lens is held in a sealed environment;
 - f) sterilizing the envelope and contents;

5

- f) allowing access to said lens by splitting, peeling or dividing said package along at least one edge.
- 28 A single use package for retaining a contact lens: the package comprising at least one barrier material defining an internal space for holding a contact lens; a medium in the space for maintaining lens hydration; means to enable release of the lens from said space; wherein the at least one barrier layer is formed from a homogenous, pliable material.
 - 29 A package according to claim 28 wherein the barrier material is pliable allowing the package to be deformed, flattened, twisted, bent, crushed folded or rolled in unison with the lens therein and without compromise to the integrity of the lens...
- 30 A set of single use retort packages for holding contact lenses therein; the
 20 packages each comprising at least one layer of flexible/pliable package material
 forming at least first and second opposing surfaces which define an internal
 package space in which the contact lens is retained;
 - a medium in the space for maintaining lens hydration; and

means for enabling release of said contact lens from said package; wherein the package material is capable of assuming a generally planar configuration and is not preformed; wherein the set is formed by joining at least two said packages end to end so that a single package may be torn away from an adjacent package via a frangible connection between the packages.

31 A single use, pliable retort package including an internal space for holding a contact lens and a medium for maintaining lens hydration therein.

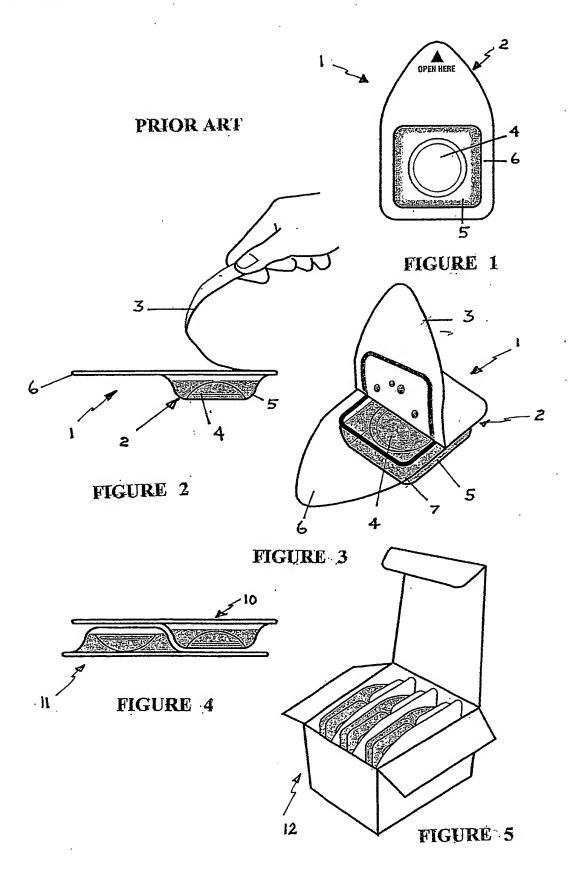
5

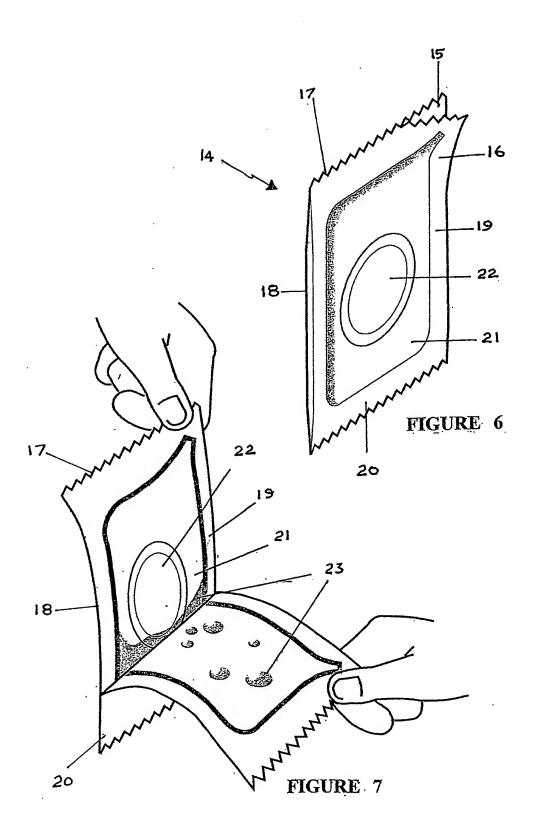
10

- 32 A package according to claim 31 wherein, the pliability of the retort package enables the package to be rolled, folded, bent, twisted or flattened in unison with the lens without damage to the lens.
- 33 A single use package for retaining a contact lens therein: the package comprising at least one package wall defining an internal space for holding the contact lens; a medium in the space for maintaining lens hydration; means to enable release of the lens from said space; wherein the at least one wall is formed from a homogenous or multi layer, pliable material.
- 34 A single use package according to claim 33 wherein the homogenous material is a single layer.
- 35 A single use package according to claim 34 wherein the multi layer package material includes a metallic layer of aluminium.
- 36 A single use package according to claim 35 wherein the internal space is defined by opposing walls which each have sufficient pliability to enable rolling, folding, twisting flattening of the package without damage to the lens.

37 A single use package according to claim 33 wherein the lens is released from the package by peeling one layer from another layer.

38 A kit of joined single use pliable retort packages for each holding a contact lens; wherein each single use package is connected to at least one adjacent package.





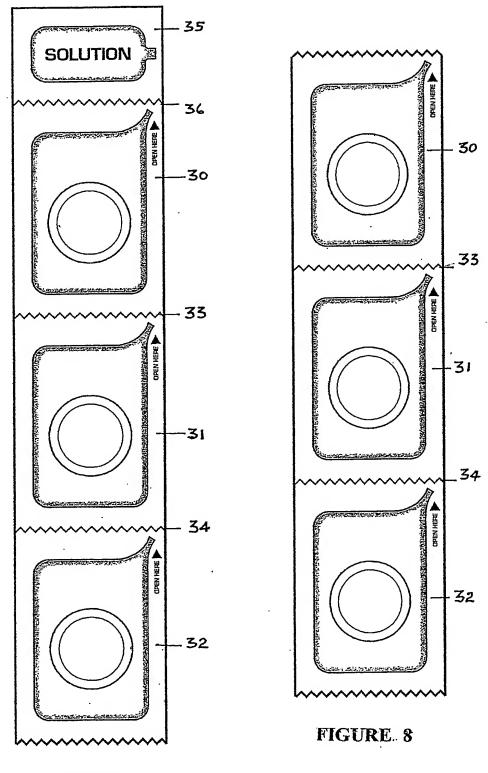


FIGURE 9

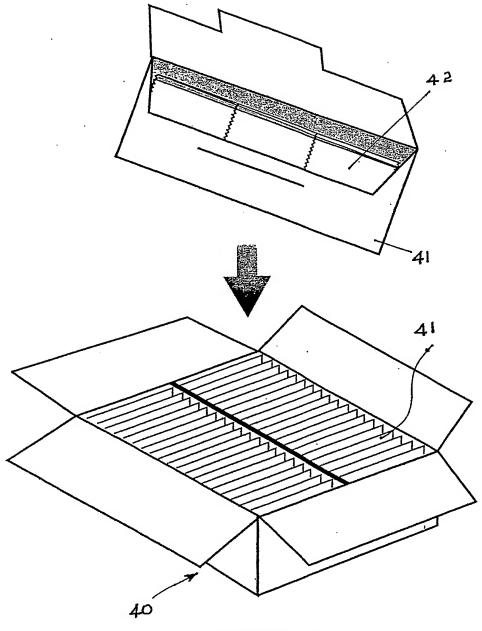


FIGURE 10

International application No.

PCT/AU02/01105

Α.	CLASSIFICATION OF SUBJECT MA	TTER		
Int. Cl. 7:	B65D 85/38, 75/30, G02C 7/04, A45C	11/00		
According to	International Patent Classification (IPC) or	to both	national classification and IPC	
В.	FIELDS SEARCHED			
Minimum docu Refer to elec	mentation searched (classification system follow tronic database consulted below	wed by c	assification symbols)	
Documentation	searched other than minimum documentation t	to the ext	ent that such documents are included in the fields search	ned
DWPI: IPC I pack, envelo	base consulted during the international search B65D, A45C 11/00, A61J 1/-, G02C 7/ pe, pouch, flexible, pliable; and similal stact and lens and (flexible or retort) are	/04 and ir terms	·	s, hydrate,
	ontact and lens and (flexible or retort)	_		
C.	DOCUMENTS CONSIDERED TO BE REI	LEVANI	•	
Category*	Citation of document, with indication, w	here app	propriate, of the relevant passages	Relevant to claim No.
P,X	US 2002/0029984 A (HUGHES) 14 See figure 2	March	2002	1-30
X	US 5697495 A (ABRAMS ET AL) Figures 2-5	16 Dece	ember 1997	31-38
x	EP 1092645 A (JOHNSON & JOHN See figures	V MOSV	/ISION CARE INC.) 18 April 2001	31-37
F	further documents are listed in the conf	tinuatio	n of Box C X See patent family ann	ex
"A" docume which i relevan after th "L" docume claim(s publica reason "O" docume exhibit	which is not considered to be of particular relevance and not in conflict with the application but cited to understand the print or theory underlying the invention after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) and not in conflict with the application but cited to understand the print or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document of particular relevance; the			
	ent published prior to the international filing at later than the priority date claimed			
Date of the act	ual completion of the international search		Date of mailing of the international search report	28 NOV 2002
	ling address of the ISA/AU	· · · · · · · · · · · · · · · · · · ·	Authorized officer	
AUSTRALIAN PO BOX 200, E-mail address	N PATENT OFFICE WODEN ACT 2606, AUSTRALIA : pet@ipaustralia.gov.au (02) 6285 3929		A. ALI Telephone No: (02) 6283 2607	

International application No.

PCT/AU02/01105

Box I	Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)			
This inter	mational search report has not been established in respect of certain claims under Article 17(2)(a) for the following			
1.	Claims Nos:			
	because they relate to subject matter not required to be searched by this Authority, namely:			
2.	Claims Nos: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:			
3.	Claims Nos: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)			
Box II	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)			
This Inte	rnational Searching Authority found multiple inventions in this international application, as follows:			
The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:				
	See extra sheet at the end of report			
1.	As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims			
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.			
3.	As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:			
4.	No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:			
Remark	on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.			

International application No.

PCT/AU02/01105

Supp	lement	tal Box
------	--------	---------

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No:

- 1. Claims 1-27, 30 define a single use package capable of holding a contact lens therein. It is considered that at least one barrier layer of flexible/pliable material defining an internal space, the barrier layer not preformed potentially represents a "first special technical feature".
- 2. Claim 28 and 29 define at least one barrier layer material defining an internal space but not restricting the material to being not preformed.
- 3. Claims 31 and 32 define a single use retort package including an internal space but not limiting the at least one barrier layer material to be not preformed.
- 4. Claims 33-37 define a single use package comprising at least one package wall defining an internal space. These claims appear to include within their scope prior art blister packs with preformed recesses.

There are numerous examples of packages of this type. For example, see :

US 5609246, US 5409104, GB 2222816, FR 2638248

5. Claim 38 defines a kit of joined retort packages not limited to at least one barrier layer defining an internal space, the material not being preformed.

Information on patent family members

International application No.

PCT/AU02/01105

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2002/0029984		NONE				
US	5697495	AU	77599/94	BR	9404326	CN	1111115
		CZ	9402688	EP	650676	FI	945148
		HK	1003078	HU	71959	${ m I\!L}$	111481
		NO	944155	NZ	264840	ZA	9408597
		US	5620088	US	5823327	US	5983608
		JР	8005971	AU	50390/96	EP	734965
		JР	9023916	SG	64898	AU	50391/96
		EP	734964	JР	9047312	SG	52616
EP	1092645	AU	200066489	BR	200004782	CN	1312481
		JP	2001171757				
							END OF ANN